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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,660	10/11/2005	Yan Hong	2577-158	1905
6449 7590 07/05/2007 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER KIM, YOUNG J	
			ART UNIT 1637	PAPER NUMBER
			NOTIFICATION DATE 07/05/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/552,660

Applicant(s)

HONG, YAN

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/11/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The IDS received on May 11, 2006 is acknowledged.

The signed copy of PTO-1449 is enclosed herein.

Drawings

The drawings received on October 11, 2005 are acceptable.

Claim Objections

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 serves as a parent claim for claim 22. Claim 21 defines the detection enzyme means as comprising a luciferase-luciferin-based enzymatic reaction. However, claim 22 recites that said means comprise ATP sulfurylase and luciferase, thus not including luciferin in the parent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase, "the sample DNA."

There is insufficient antecedent basis for this limitation in the claim. It would appear that the phrase, “the sample target nucleic acid” would find a proper antecedent basis. However, if such phrase is adopted, Applicants are advised that the rest of the limitation present in claim 1, and claims 9, 12 and 13, should also reflect the same phrase for proper antecedent basis.

Claims 2-19 are indefinite by way of their dependency on claim 1.

Claim 6 recites the term, “substantially simultaneously.”

Claim language such as this is indefinite in its metes and bounds, as one cannot properly determine whether something substantially simultaneously is sequentially done or not.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 11, 12, 14, 15, and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Murray et al. (WO 02/064830 A3, published August 22, 2002).

Murray et al. disclose a method of identifying the presence of a target nucleic acid in a sample (page 6, lines 3-9), wherein the method involves a replication of the target nucleic acid, said method comprising the steps of:

a) detecting the pyrophosphate (PPi) produced by a nucleic acid polymerase enzyme in the presence of dCTP, dGTP, dTTP, primer(s), a DNA template (page 5, lines 21-24); and

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b) detecting the presence of the target nucleic acid by using the generated PPi in a bioluminescence reaction involving ATP sulfurylase and luciferase (page 5, lines 10-15), thereby clearly anticipating claims 1, 2, 3, 5, and 12.

With regard to claim 4, the artisans explicitly disclose the use of luciferin, luciferase enzymes in their bioluminescence reaction (page 8, lines 29 and 30).

With regard to claim 6, the artisans explicitly disclose that the reaction is performed, “directly on the reaction mixture used for the enzyme DNA synthesis (i.e., PCR) in the presence of all the components necessary for DNA synthesis (page 5, lines 13-15).

With regard to claims 7 and 8, the artisans explicitly employ a d- α -S-ATP (alpha-thio-dATP; see page 6, lines 21-30).

With regard to claims 11, 14, and 15, the artisans explicitly disclose the use of a *Taq* polymerase, which is known and accepted in the art as being thermostable (page 9, line 30), and wherein the artisans explicitly disclose that their method is for the purpose of detecting pathogens in a sample.

With regard to claims 20, 21, and 22, the artisans explicitly disclose a kit comprising the reagents necessary for their subject method (see claim 17).

Therefore, the invention as claimed is clearly anticipated by Murray et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. (WO 02/064830 A3, published August 22, 2002) in view of Nyren et al. (U.S. Patent No. 6,258,568, issued July 10, 2001, priority July 23, 1999).

The teachings of Murray et al. have already been discussed above.

Murray et al. do not explicitly disclose that the sample DNA or oligonucleotide be immobilized to a solid support, or that a multiplicity of sample DNA sequences are arranged in an assay format on a solid surface.

Murray et al. do not explicitly disclose the use of a exonuclease deficient high fidelity polymerase.

Nyren et al. disclose a bioluminescence assay employing pyrophosphates (ELIDA), said bioluminescence involving the same luciferase, ATP sulfurylase enzymes, wherein the artisans explicitly disclose the immobilization of the DNA on a solid surface (column 7, lines 57-59) or that the primers are immobilized on a solid surface (column 8, lines 16-18).

Nyren et al. also employs a exonuclease deficient high fidelity polymerase (see claim 14).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Murray et al. with the teachings of Nyren et al., thereby arriving at the claimed invention. One of ordinary skill in the art would have been motivated to employ the solid phase format disclosed by Nyren et al., in the method of Murray et al, for the well-known advantage of the solid phase format allowing a plurality of assays to take place simultaneously. In addition, one of ordinary skill in the art would have well recognized that the use of a high fidelity polymerase in an amplification would have benefited said one of ordinary skill in the art, as one of ordinary skill in the art would have desired to preclude erroneous amplification of the target nucleic acid in their method of amplification.

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Given the fact that Nyren et al. was capable of employing the same reagents employing a exonuclease deficient, high fidelity polymerase in their reaction, one of ordinary skill in the art would have had a reasonable expectation of success at producing the combination, rendering the invention as claimed *prima facie* obvious over the cited references.

Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. (WO 02/064830 A3, published August 22, 2002) in view of Segev (WO 96/34984, published November 7, 1996).

The teachings of Murray et al. have already been discussed above.

Murray et al. do not explicitly disclose that the nucleic acid is viral, or that the nucleic acid sample is obtained from food source, said source being plant, said nucleic acid being non-native to the sample.

Segev evidences the art-recognized desire to detect non-native pathogens, such as virus in, for example plants (page 1, lines 24-26; page 4, lines 4-7).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Murray et al. for the detection of viral nucleic acids or virus in samples such as plants, for the well known desire to detect the presence of pathogens, food-borne pathogens, for the survival of mankind.

Conclusion

No claims are allowed.

Inquiries

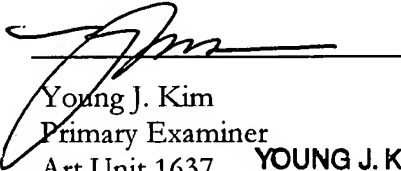
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is

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on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.


Young J. Kim
Primary Examiner
Art Unit 1637
6/18/2007

YOUNG J. KIM
PRIMARY EXAMINER

YJK